

**REMARKS**

Claims 124-130 and 143-149 are pending in the application. Claims 124, 125, 128, 130, 143, and 147 are amended for clarity and to correct informalities, as discussed herein. No new matter is introduced. The office action is discussed below:

***Response to Arguments and Anticipation Rejection:***

On pages 2-8 of the Office Action, the examiner states that the arguments filed on December 21, 2011 are not persuasive and maintains the anticipation rejection on pages 9-10.

The examiner maintains that Shen et al. (6,228,900, having an effective filing date of 07/09/1996) disclose the instantly claimed process steps and, thus, the products obtained by the process steps. The examiner also maintains that Hyon et al. (6,168,626, having an effective filing date of 05/06/1996) disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point and cooling, i.e., the steps set forth in instant process claim 147 and in instant claim 128 for obtaining the claimed product.

Applicants respectfully disagree with the examiner and submit following explanations in order to assist the examiner in finding the facts that the claimed methods were reduced to practice prior to the effective filing date of the cited references.

Applicants also submit that the claimed methods were reduced to practice prior to the effective filing date of the cited references as evidenced by the declarations on the record. Applicants submit, since the Saum *et al.* (U.S. Patent No. 6,017,975) process was found patentable over prior art at the time of its claimed effective filing date, the instant claims, which are copied from Saum, also should be patentable. The instant claims were copied from the Saum *et al.* (U.S. Patent No. 6,017,975) patent,

which is the target patent for an interference.

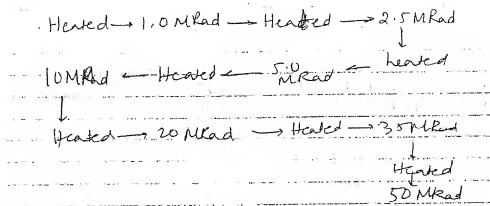
The examiner states that the priority application 08/726,313 discloses a method wherein the UHMWPE is irradiated and then heated and a method wherein the UHMWPE is melted and then irradiated, so the instant claims are considered to have a filing date of October 2, 1996. Applicants disagree with the examiner and point out that not all methods disclosed in the specification require "a melting" step. However, in order to expedite the prosecution, applicants amend the independent claims to clarify that all UHMWPE material had a melt-history prior to irradiation. Accordingly, applicants amend the independent claims 124, 125, 128, 130, 143, and 147 to recite that "the UHMWPE was heated above the melting point prior to irradiation".

In addition, applicants point out that the currently amended claims recite that the irradiated UHMWPE material is heated above the melting point and the starting UHMWPE material was also heated above the melting point prior to irradiation. Therefore, in view of the specification and the declaration of Merrill *et al.* the claimed invention was reduced to practice before January 20, 1995.

The examiner agreed that UHMWPE sample was heated (melted) in a chamber and that an electron beam was irradiated into the chamber through the thin foil at top such that a maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. The examiner also accepted that irradiation was done using a van de Graaff generator with electrons of energy 2.5 MeV and a dose rate of 1.67 Mrad/min, the heating was stopped and the sample allowed to cool to room temperature in the chamber after irradiation. However, the examiner opines that Example 6 does not mention placing the chamber containing the sample on a conveyor belt or moving the chamber on a conveyor belt during irradiation or heating the irradiated UHMWPE sample to melt (150°C or above) after free radicals have been formed by irradiation and before cooling. The examiner also opines that the method described in Example 6 does not suggest a process starting with irradiation to form free radicals and followed by heating to 150°C or above after irradiation to form crosslinks before cooling. Applicants explain that formation of free radical is inherent while the examiner agreed that irradiation was carried out. Likewise, the examiner admitted that the UHMWPE was

heated (melted), which means the heating temperature was above the melting point, and 150°C or above are within such scope.

Again the examiner admits that the "Example 6 is an example of the disclosed process of melting UHMWPE and then irradiating the UHMWPE in the melt, followed by cooling." However, asserts that "the instantly recited steps of irradiating an UHMWPE fabricated article followed by heating the irradiated article are not disclosed in Example 6 of 08/600,744." Applicants disagree with the examiner, and point out that one skilled in the art would appreciate that the process using van de Graaff generator, as explained above and as described in the specification, including Example 6, involves step by step process of irradiation, heating and cooling. In this regard, applicants request the examiner to considering Dr. Orhun Muratoglu's declaration submitted in a related application, Serial No. 11/184,803. In the declaration, Dr. Muratoglu reviewed the Rule 1.131 declaration, filed on July 16, 2004, and found that Exhibit 3 of the declaration clearly shows that the Experiment 2 describes step by step process of heating and continued irradiation and heating (see below, as reproduced from the Exhibit 3):



It is therefore clear to the skilled persons and lay persons alike from the above sketch that the process involved repeated heating and radiation and the cross-linked material can be cooled after a desired radiation dose is received.

With respect to the inherent functions and properties of a van der Graaff generator, the examiner opines that the arguments and comments are not considered to be relevant to the instant claimed process or products, because, the instantly claimed

process does not require a conveyor belt or passing the sample through an electron beam to apply multiple doses or heating between doses. Applicants disagree with the examiner and submit that it is not necessary to recite the name or parts of the machine. One skilled in the art would understand that the recited process steps, such as repeated steps of irradiation, heating and cooling, as evident from the photographs, filed on November 19, 2009, which are the photographs of the van der Graaff generator rather are the photographs of any van de Graaff generator that could be used to irradiate the UHMWPE sample.

Thus, the use of the van der Graaff generator in Example 6 discloses a process wherein the polyethylene is repeatedly heated and irradiated, thus providing evidence that the Example 6 process inherently requires irradiating followed by heating. Therefore, the use of a van der Graaff generator in Example 6 inherently discloses the instantly recited process steps and establishes an effective filing date of 02-13-1996 for the instant claims. The instantly claimed process steps are required to be in order of irradiating, then heating and then cooling while the process steps in disclosed in 08/600,744 Example 6 are required to be in the order heating, then irradiating and then cooling.

Thus, the evidence presented in the Rule 1.131 Declaration of Merrill *et al.* filed November 19, 2009 shows reduction to practice of the claimed invention before January 20, 1995. Regarding support from the specification as filed, applicants submit that:

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971), *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973).

See MPEP §2163.07 (a) (Rev. 6, September 2007 at 2100-192).

Therefore, in accordance with the above cited relevant passage in the MPEP with respect to inherent functions or properties in a disclosure, as asserted by the

examiner, the specification and the Declaration provide sufficient disclosure to establish inherency, the extrinsic evidence that made it clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill Inherency. The examiner also asserts that "mere fact that a certain thing may result from a given set of circumstances is not sufficient". In the instant case, applicants point out that it was not a mere fact that a van de Graaff generator may be used in a conveyor method, rather the evidence of the van de Graaff generator used in the experiment sufficiently presented to establish that it was used in such a method in Example 6 disclosed in SN 08/600,744.

Thus, the claimed method was reduced to practice using the van de Graaff generator, which inherently involves heating of the irradiated materials as described in the specification as filed.

Regarding the priority issue, applicants refer to the declaration of Merrill *et al.* that the claimed invention was reduced to practice before January 20, 1995. Specifically, applicants refer to sections 5 and 10 of the declaration that provide evidences of the conception and reduction to practice of the recited method steps. For example, in the section 5 of the declaration, item b) of Exhibit 1 establishes that prior to January 20, 1995, inventors conceived and reduced to practice a process in which UHMWPE bar stock had been "irradiated and then heated above the melting point". Applicants also quote from the declaration, for example, the inventors state at section 10 of the declaration that "Prior to January 20, 1995, we also developed another embodiment to preserve the highly disordered entangled state of the UHMWPE in order to solve the wear problem (see item b of Exhibit 1). The embodiment involved cross-linking the polyethylene in at room temperature ('cold irradiation') by irradiation and subsequent melting. The process is referred to as Cold-irradiation and Subsequent Melting or "CISM" and is disclosed in U.S. Serial No. 08/726,313 ...." Hence, a method that involves irradiation is followed by subsequent heating to 150°C or above to treat a UHMWPE was reduced to practice before January 20, 1995. Accordingly, Hyon is not a prior art to the claimed invention.

Applicants also refer the examiner to Dr. Orhun Muratoglu's declaration in a related U.S. Patent Application No. 11/184,803, in which Dr. Muratoglu reviewed Rule 1.131 Merrill declaration, and found that Irradiation and Subsequent Melting embodiment was conceived and reduced to practice prior to January 20, 1995.

In view of the above explanations, applicants submit that Shen *et al.* and Hyon *et al.* are not prior art to the claimed invention.

Regarding the declaration of Dr. Orhun Muratoglu, the examiner agreed that the referred Experiment 2 provide evidence of a process requiring repeated steps of heating and irradiating consolidated polymer using a van der Graaff generator. However, the examiner asserts that the evidence is not persuasive because the instantly claimed process does not include heating to a temperature above 150°C before irradiation, multiple heating and irradiation steps and an irradiation step before the cooling step. Applicants disagree with the examiner and refer to above explanation that not all methods disclosed in the specification require "a melting" step. However, in order to expedite the prosecution, applicants amend the independent claims to clarify that all UHMWPE material had a melt-history prior to irradiation. Accordingly, applicants amend the independent claims 124, 125, 128, 130, 143, and 147 to recite that "the UHMWPE was heated above the melting point prior to irradiation".

In addition, applicants point out that the currently amended claims recite that the irradiated UHMWPE material is heated above the melting point and the starting UHMWPE material was also heated above the melting point prior to irradiation.

***Claim Interpretation and Effective Filing Date:***

On page 8 of the Office Action, the examiner maintains that claims 124-127, 130 and 143-149, recite a process wherein irradiation of UHMWPE is subsequently followed by heating or melting: a method ("IR-SM") first disclosed in 124-127, 130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996, which is the filing date of the priority application SN 08/600,744.

Therefore, the examiner maintains that the earliest effective filing date of the instant claims 124-127, 130 and 143-149, wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the October 2, 1996 filing date of SN 08/726,313.

Applicants disagree with the examiner and submit, as discussed above and as evidenced by the declaration and the Exhibits, that the instantly claimed embodiment, wherein heating of the irradiated materials at 150°C or above and cooling thereafter, was reduced to practice prior to January 20, 1995. Applicants explain, not all methods disclosed in the specification require "a melting" step. However, in order to expedite the prosecution, applicants amend the independent claims to clarify that all UHMWPE material had a melt-history prior to irradiation. Accordingly, applicants amend the independent claims 124, 125, 128, 130, 143, and 147 to recite that "the UHMWPE was heated above the melting point prior to irradiation".

Regarding claims 128-129, applicants submit that the currently amended claims 128 recite that "the UHMWPE was heated above the melting point prior to irradiation", thus, as discussed above, the claimed process was reduced to practice prior to January 20, 1995. Claim 129 is dependent of claims 128. Accordingly, withdrawal of the rejection is requested.

#### ***Double Patenting Rejections:***

On pages 10-12 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263.

Applicants reiterate, since a notice of allowability has not been issued for any of the U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01, more specifically, see MPEP § 804 I.B.

#### ***Between Copending Applications-Provisional Rejections***

Occasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications ( 35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Accordingly, the provisional double-patenting rejection over the co-pending U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263 should be withdrawn.



**REQUEST**

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at 202-652-6200 should there be any questions.

Respectfully submitted,



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